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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,641	04/01/2005	Makoto Asakawa	SHIM1100	6517

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,641	ASAKAWA ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-21 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record in the previous Office Action (Mailed 1/16/07) and for reasons outlined below.

Applicants traverse this rejection by asserting that "literal" support for a claim limitation is not necessary for fulfilling the written description requirement. Applicants assert that the claimed invention is based upon the transfer of a foreign gene and that in Example 6, applicants demonstrate detection of the transfer. Applicants also assert that since techniques for the detection of a foreign gene are routine in the art (as indicated by the examiner in the accompanying 103(a) rejection), said methods need not be disclosed in the specification.

Applicant's arguments filed 6/18/07 have been fully considered but they are not persuasive. First, while literal support in the specification for a claimed limitation is not required, some support for said claimed limitation must be present. Applicants' arguments that detection of the foreign gene must have been made because Example 6

demonstrates this detection is not persuasive. Example 6 does not demonstrate "[d]etecting the presence of **the foreign gene** (emphasis added) in the second cell", only detecting the size and shape of plaques formed by M deletion (or defect) type cDNAs. While the plaques formed by the M deleted (or defective) viral DNAs are a characteristic of cells wherein viral DNA is replicating, merely observing plaque size and shape is not equivalent to detecting the presence of **a foreign gene** transferred to a second cell.

Second, with regard to the argument that the specification need not disclose conventional techniques, it is noted that the claims recite detection of the foreign gene transferred to a second cell and hence said detection methodology is essential subject matter. Essential subject matter must be present in the specification (unless incorporated by reference to a US patent or US patent publication which does not itself incorporate essential subject matter by reference) and applicants cannot argue that it would have been obvious for the skilled artisan to use any (undisclosed) detection method for determining the presence of **a foreign gene transferred specifically into a second cell**. The claimed limitation of "detecting a foreign gene" reads on a genus of detection methods, i.e. detecting a marker or reporter gene transferred to a second cell, detecting a therapeutic gene by detection of beneficial effect on the second cell to which the gene is delivered, etc. Applicants provide no disclosure on detection of transfer of a specific foreign gene to a second cell from the first infected cell.

Finally, the claims read on detecting the presence of the foreign gene specifically in the second cell and not in the first cell. This encompasses situations in which there is

no fusion between the first and second cells and the cells remain separate. The instant specification provides no disclosure of detection methods which would discriminate between the two cells and detect a specific foreign gene transfer from the first cell to the second.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Magai et al. in view of Zhang et al. or Nabel et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants assert that "[t]he Examiner's arguments rely on the assumption that the skilled artisan would have recognized that the gene transfer from the first cell to the second cell is merely a "success" of the use of the conventional viral vector, and he/she would have "expected" this transfer. However, none of Nagai, Zhang, or Nabel supports this assumption." Applicants assert that Magai et al. is silent with regard to the ability of the virus to transfer the transgene from the infected cell to the neighboring cell by cell-to-cell contact. Applicants assert that Magai et al. teaches away from the instant invention because Magai et al. recites that the viral complexes can replicate only within the infected cells and cannot spread from cell to cell. Since applicants assert that transfer of the transgene from the first to the second cell would not have been a success of the method, the skilled artisan would not have been motivated to detect the presence of the foreign gene in the second cell and the skilled artisan would not have had a reasonable expectation of success in detecting the presence of the foreign gene in the second cell. Applicants indicate that the court in *In re Marshall* held that a compound's known disadvantages, which would naturally discourage search for new uses of that compound, may be taken into account in determining obviousness and that since Magai et al expressly teaches away from the claimed invention by indicating that the complexes can "... replicate only within infected cells but not spread from cell to cell...", the Office has not established a *prima facie* case against the claimed invention.

Applicants' arguments have been considered but are not found persuasive. It is clear from the disclosure of Magai et al. that the complexes recited therein are deficient in disseminative capability in that cells containing said complexes are incapable of

producing infectious virus particles but that the cells are capable of transferring a transgene from the infected cell to a neighboring cell by contact. The examples disclosed by Magai et al. involve Sendai virus in which the M gene is deleted but other genes such as the fusion protein encoding gene (F protein) are intact (see for example Fig. 1) and the complex has autonomous replicating ability. The cells comprising the complex are not capable of producing virus (See Fig. 1C in Magai et al.) but the complex is capable of expressing the F protein as well as the HN protein, etc. and hence the infected cells are capable of introducing the transgene contained in the complex to a neighboring cell by contact through fusion of the infected cell and neighboring cells mediated by the expressed F protein. The portions of the Magai et al. reference which applicants indicate teach away from the claimed invention refer to the inability of the complexes to produce infectious virus particles and hence the inability of the complexes to spread from cell to cell by virus infection. Given the presence of the Sendai F and HN genes in the contemplated RNA complexes, the ordinary skilled artisan would have known that the host cells comprising said complex would be able to fuse with neighboring cells by virtue of the expressed Sendai virus F and HN proteins and hence transfer the transgene to the neighboring cell(s). The detection of successful transgene transfer to host cells would have necessarily involved detecting the presence of the transgene in the second cell because the second cell would have fused with the first cell, so that any detection of the presence of the transgene would involve detection of the transgene in the second cell.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
August 27, 2007

DAVID GUZO
PRIMARY EXAMINER